Medacta
International

510(k) Summary

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NOV 0 4 2013

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Date Prepared: May 27, 2013

DEVICE INFORMATION

Trade/Proprietary Name: Mectacer Biolox Option Heads
Common Name: Ceramic Femoral Heads

Classification Name: Hip Joint, metal/ceramic/polymer, semi-constrained, cemented or non-porous, uncemented prosthesis

21 CFR 888.3353
Class II
Device Product Codes: LZO

Predicate Devices:

510(k)	Product	510(k) Holder	Clearance Date
K073337	MectaCer Biolox Forte Heads	Medacta International	2/13/2008
K112115	MectaCer Biolox Delta Heads	Medacta International	10/7/2011
K082996, K093549	Biolox Delta Option Ceramic Heads	Biomet	1/15/2009, 12/16/2009

Product Description

The Mectacer Biolox Option Heads consist of a metal sleeve made of titanium alloy Ti-6Al4V according to ISO 5832-3 and ASTM F136 in neck lengths of S, M, L, and XL with an inner 12/14 taper and a MectaCer BIOLOX® OPTION ceramic femoral head (made of BIOLOX® delta ceramic) with head diameters of 28, 32, 36, 40, and 44mm with a conical bore which matches with the external taper of the sleeve. The MectaCer BIOLOX® OPTION femoral heads are made of high-purity aluminium oxide Al_2O_3-ZrO_2 ceramic compound according to ISO 6474-2. The pink color is due to the chromium oxide (Cr_2O_3) that improves the hardness of the composite material.

Indications for Use

The MectaCer BIOLOX® OPTION femoral heads are intended for mechanical fixation to a mating hip stem and indicated for treatment of patients who are candidates for total or partial hip arthroplasty in primary or revision surgery.
The patient should be skeletally mature.

The patient's condition should be due to one or more of the following:

- Severely painful and/or disabled joint as a result of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or psoriatic arthritis,
- Congenital hip dysplasia,
- Ankylosing spondylitis,
- Avascular necrosis of the femoral head,
- Acute traumatic fracture of the femoral head or neck,
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement where sufficient bone stock is present.

Comparison to Predicate Devices

The indications for use, design features and materials of the Mectacer Biolox Option Heads are substantially equivalent to those of the predicate devices. The safety and effectiveness of the Mectacer Biolox Option Heads are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Performance Testing

The Mectacer Biolox Option Heads were tested for fretting corrosion of the metallic sleeve and the tapers of the femoral stems. These tests were conducted on Ti6Al7Nb (ISO 5832-11) femoral stems. In addition, the Mectacer Biolox Option Heads were tested for burst strength, fatigue, post-fatigue, pull-off and rotational stability.

A review of the mechanical data indicates that the MectaCer Biolox Delta Heads are equivalent to devices currently cleared for use and are capable of withstanding expected in vivo loading without failure.

Conclusion:
Based on the above information, the Mectacer Biolox Option Heads can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 4, 2013

Medacta International SA
% Mr. Adam Gross
Director of Regulatory, Quality and Compliance
Medacta USA
4725 Calle Quetzal, Unit B
Camarillo, California 93012

Re: K131518
Trade/Device Name: Mectacer Biolox Option Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: October 4, 2013
Received: October 7, 2013

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131518

Device Name: Mectacer Biolox Option Heads

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Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices